

ABSTRACT

The sterilization method disclosed includes the steps of

- providing a sterilization chamber;
- placing the article into the sterilization chamber;
- equalizing the temperature of the article and the sterilization atmosphere;

sealing the sterilization chamber;

- applying a vacuum of a preselected vacuum pressure to the sterilization chamber;
- supplying water vapour to the sterilization chamber under vacuum;
- supplying ozone-containing gas to the sterilization chamber;
- maintaining the sterilization chamber sealed for a preselected treatment period; and
- releasing the vacuum in the sterilization chamber;

whereby a vacuum pressure is used which lowers the boiling temperature of water in the sterilization chamber below the temperature in the sterilization chamber. One or more ventilating cycles can be added to the preferred method for removing the remaining ozone and humidity from the sterilization chamber. Single cycle sterilization with ozone is more efficient and provides for a shorter sterilization cycle than with ETO and requires few changes in user habits. Moreover, the ozone-based process in accordance with the invention is compatible for use with current packaging, such as sterile pouches and rigid containers. The sterilization process is simple and substantially avoids human errors caused by false interpretation and handling. The ozone sterilization method of the invention requires substantially no aeration or cooling down of sterilized instruments so that they can be used immediately following the

sterilization cycle. This allows hospitals to reduce the cost of maintaining expensive medical device inventories.

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